AUROQUIL COLD AND FLU NIGHTTIME RELIEF - acetaminophen, doxylamine succinate, and dextromethorphan hbr solution Aurohealth LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients (in each 30 mL dose cup)

Purpose

Acetaminophen, USP 650 mg Dextromethorphan HBr, USP 30 mg Doxylamine succinate, USP 12.5 mg Pain reliever/fever reducer Cough suppressant Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

Warnings

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

• to make a child sleep

Ask a doctor before use if you have

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed see Overdose warning
- use dose cup or tablespoon (TBSP)
- do not exceed 4 doses (120 mL) (8 TBSP) per 24 hours
- mL = milliliter; TBSP = tablespoon

| adults & children 12 years & over | 30 mL (2 TBSP) every 6 hours |
|-----------------------------------|------------------------------|
| children 4 to under 12 years | ask a doctor |
| children under 4 years | do not use |

• When using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Other information

- each 30 mL dose cup contains: potassium 5 mg, sodium 37 mg
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

acesulfame potassium, alcohol, anhydrous citric acid, D&C yellow no. 10, FD&C green no. 3, FD&C yellow no. 6, flavors, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or Comments?

1-855-274-4122

Distributed by: **Aurohealth LLC.** 2572 Brunswick Pike, Lawrenceville, NJ 08648

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 6 FL OZ (177 mL Bottle)

AUROHEALTH

Compare to the active ingredients in Vicks[®] NyQuil[®] Cold & Flu*

NDC 58602-137-18

AuroQuil COLD & FLU Nighttime Relief

Each dose (per 30 mL) (2 TBSP) of oral solution contains: 650 mg - **Acetaminophen** USP (Pain reliever/fever reducer) 12.5 mg - Doxylamine succinate USP (Antihistamine) 30 mg - Dextromethorphan HBr USP (Cough suppressant)

- Aches, Fever & Sore Throat
- Sneezing, Runny Nose
- Cough

Alcohol 10%

6 FL OZ (177 mL)

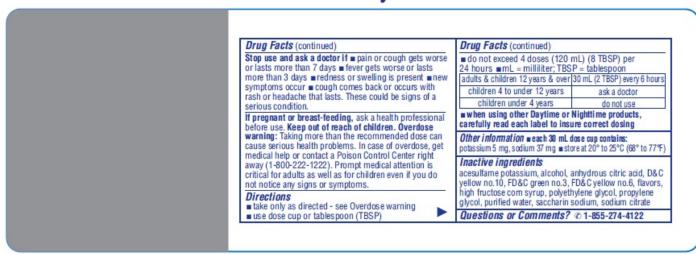
Front



Back



Bottom Ply



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 8 FL OZ (237 mL Bottle)

AUROHEALTH

Compare to the active ingredients in Vicks[®] NyQuil[®] Cold & Flu*

AuroQuil COLD & FLU Nighttime Relief

Each dose (per 30 mL) (2 TBSP) of oral solution contains:

650 mg - **Acetaminophen** USP (Pain reliever/fever reducer)

12.5 mg - Doxylamine succinate USP (Antihistamine)

30 mg - Dextromethorphan HBr USP (Cough suppressant)

- Aches, Fever & Sore Throat
- Sneezing, Runny Nose
- Cough

Alcohol 10%

8 FL OZ (237 mL)

Front



Back

Drug Facts (continued) Drug Facts (continued) using this product. contains an MAOI, ask a doctor or pharmacist Allergy alert: acetaminophen may cause severe before taking this product. . to make a child skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash Ask a doctor before use if you have ■ liver If a skin reaction occurs, stop use and seek disease glaucoma cough that occurs with too much phlegm medical help right away. (mucus) ■ a breathing problem or chronic Sore throat warning: If sore throat is severe, cough that lasts or as occurs with smoking, lasts for more than 2 days, occurs with or is asthma, chronic bronchitis or emphysema followed by fever, headache, rash, nausea, trouble urinating due to enlarged prostate or vomiting, see a doctor promptly. gland a sodium-restricted diet Do not use with any other drug containing Ask a doctor or pharmacist before use if you acetaminophen (prescription or nonprescription). are taking sedatives or tranquilizers If you are not sure whether a drug contains taking the blood thinning drug warfarin acetaminophen, ask a doctor or pharmacist. When using this product a do not use more if you are now taking a prescription than directed excitability may occur, monoamine oxidase inhibitor (MAOI) (certain especially in children marked drowsiness

drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug

may occur avoid alcoholic drinks be careful when driving a motor vehicle or operating machinery alcohol, sedatives, and tranquilizers may increase drowsiness

Bottom Ply

Drug Facts (continued)

Stop use and ask a doctor if m pain or cough gets worse or lasts more than 7 days m fever gets worse or lasts more than 3 days m redness or swelling is present m new symptoms occur m cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. Overdose warning: Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

■ take only as directed - see Overdose warning
■ use dose cup or tablespoon (TBSP) ■ do not
exceed 4 doses (120 mL) (8 TBSP) per 24 hours
■ mL = milliliter; TBSP = tablespoon

Drug Facts (continued)

| adults & children 12 years & over | 30 mL (2 TBSP) every 6 hours |
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| children under 4 years | do not use |

■when using other Daytime or Nightlime products, carefully read each label to insure correct dosing

Other information

- ■each 30 mL dose cup contains: potassium 5 mg, sodium 37 mg
 ■store at 20° to 25°C (68° to 77°F)
- Inactive ingredients

acesulfame potassium, alcohol, anhydrous citric acid, D&C yellow no. 10, FD&C green no. 3, FD&C yellow no. 6, flavors, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or Comments? © 1-855-274-4122

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 12 FL OZ (355 mL Bottle)

AUROHEALTH

Compare to the active ingredients in Vicks[®] NyQuil[®] Cold & Flu*

NDC 58602-137-16

AuroQuil COLD & FLU Nighttime Relief

Each dose (per 30 mL) (2 TBSP) of oral solution contains: 650 mg - **Acetaminophen** USP (Pain reliever/fever reducer)

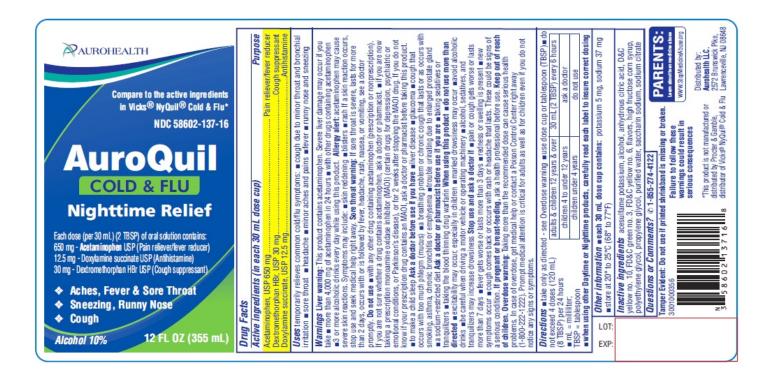
12.5 mg - Doxylamine succinate USP (Antihistamine)

30 mg - Dextromethorphan HBr USP (Cough suppressant)

- Aches, Fever & Sore Throat
- Sneezing, Runny Nose
- Cough

Alcohol 10%

12 FL OZ (355 mL)



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL TWO 12 FL OZ (355 mL Bottles)

VALUE Twin Pack

AUROHEALTH

Compare to the active ingredients in Vicks[®] NyQuil[®] Cold & Flu*

NDC 58602-137-35

AuroQuil COLD & FLU Nighttime Relief

Each dose (per 30 mL) (2 TBSP) of oral solution contains: 650 mg - **Acetaminophen** USP (Pain reliever/fever reducer) 12.5 mg - Doxylamine succinate USP (Antihistamine)

30 mg - Dextromethorphan HBr USP (Cough Suppressant)

- Aches, Fever & Sore Throat
- Sneezing, Runny Nose
- Cough

Alcohol 10%

Total 24 FL OZ (710 mL)
Two 12 FL OZ (355 mL) Bottles



AUROQUIL COLD AND FLU NIGHTTIME RELIEF

acetaminophen, doxylamine succinate, and dextromethorphan hbr solution

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58602-137 | |
| Route of Administration | ORAL | | | |

| Active Ingredient/Active Moiety | | | | |
|--|----------------------------------|---------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D) | ACETAMINOPHEN | 650 mg in 30 mL | | |
| DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 30 mg in 30 mL | | |
| DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 12.5 mg in 30 mL | | |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | | |
| ALCOHOL (UNII: 3K9958V90M) | | |
| ANHYDRO US CITRIC ACID (UNII: XF417D3PSL) | | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | | |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) | | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | | |
| ANISE (UNII: 21C2F5E8RE) | | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | | |
| HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S) | | |
| POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| WATER (UNII: 059QF0KO0R) | | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | | |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | | |
| | | |

Product Characteristics

| Color | GREEN | Score |
|----------|----------------|--------------|
| Shape | | Size |
| Flavor | ANISE, MENTHOL | Imprint Code |
| Contains | | |

| | Packaging | | | | |
|---|--------------------|---|-----------------------------|---------------------------|--|
| : | # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| | 1 NDC:58602-137-18 | 177 mL in 1 BOTTLE; Type 0: Not a Combination Product | 02/09/2015 | 10/01/2021 | |
| ŀ | 2 NDC:58602-137-20 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 02/09/2015 | 10/01/2021 | |
| | 3 NDC:58602-137-35 | 2 in 1 CARTON | 02/09/2015 | 10/01/2021 | |
| | 3 NDC:58602-137-16 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH FINAL | part341 | 02/09/2015 | 10/01/2021 |
| | | | |

Labeler - Aurohealth LLC (078728447)

Registrant - Aurohealth LLC (078728447)

| Establishment | | | | |
|----------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Aurohealth LLC | | 078728447 | MANUFACTURE(58602-137) | |

Revised: 11/2020 Aurohealth LLC